Employing a Modular and Scalable Design for Next Generation Healthcare Respiratory Protection

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Scott Safety
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Objective & Agenda

- Agenda
  - Problem Statement
  - Approach
  - HCW Needs & Benefits
  - Concept Development
  - Addressing Capability Gaps – Focus for Project BREATHE
    - Diverse Worker Population Accommodation
    - Voice Intelligibility
    - Work of Breathing
    - Tolerability/Comfort
    - Microclimate - Temperature & Humidity
  - Further Research/Next Steps

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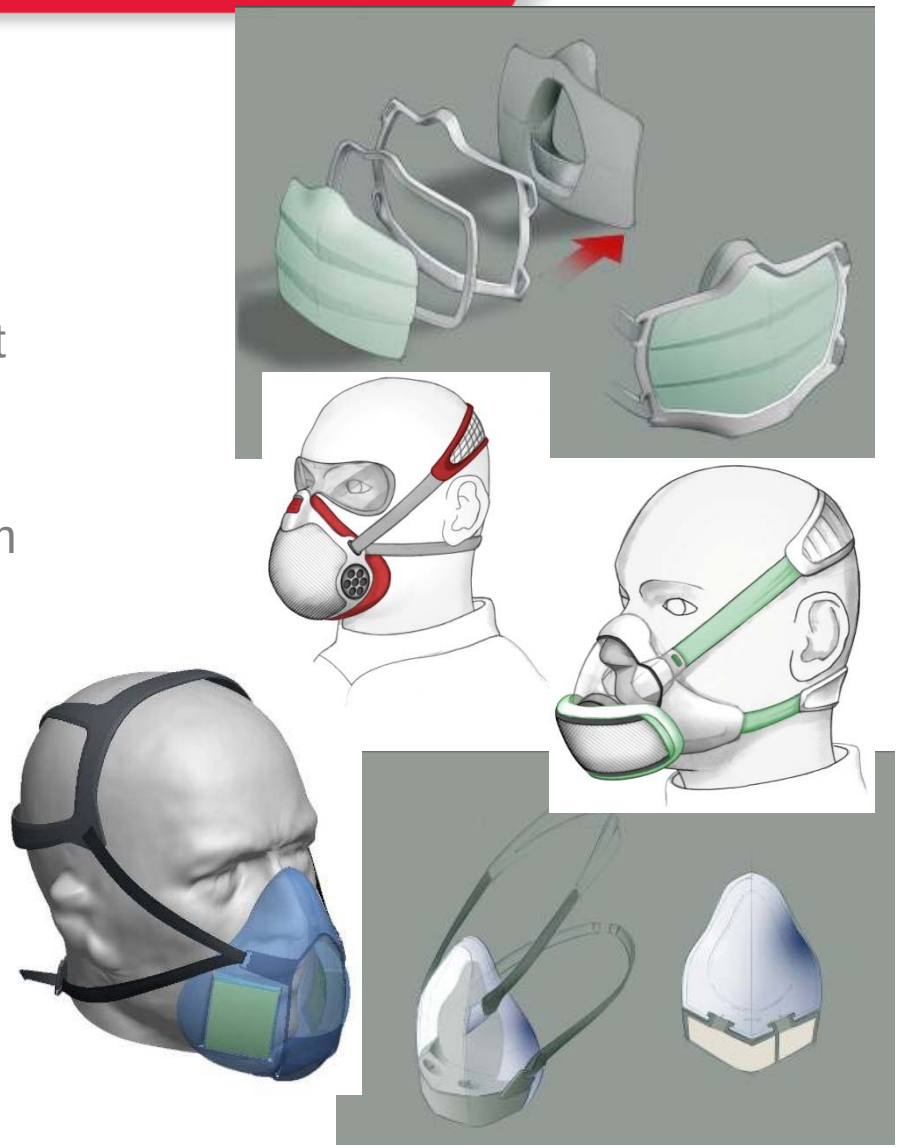
Problem Statement

Develop a next generation healthcare respirator that meets/exceeds 28 consensus requirements of Project BREATHE

- Meet purpose of RPE in healthcare - reduce risk of exposure in order to prevent human-human transmission of airborne infectious diseases
- Address guidance for influenza, aerosol generating/high risk procedures in US from WHO, CDC and FDA & influence with Project BREATHE capability
- Improve respirator comfort, tolerability & functionality – leverage findings into Next Generation Mask platforms
- Influence HCW culture & acceptance by addressing respirator capability gaps
- Evaluate novel media and embodiments
- Insight into healthcare respiratory protection market, user feedback



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Project BREATHE Approach

- Parallel Path – Modular & Scalable Designs
  - B95 (or Biological N95 Disposable) Filtering Facepiece Respirator
  - Hybrid Elastomeric B95
- Evidence Based Performance Requirements
- Focus on Comfort/Tolerability for HCW Acceptance; Prolonged Use
  - Breathing Resistance
  - Facial/Skin Irritation
  - Facial Pressure & Heat Rise
  - CO2 Buildup
  - Humidity/Microclimate
  - Weight/Profile
  - Odor
- Reduced Physiological Burden
- Integrated Product Team/Milestone Approach

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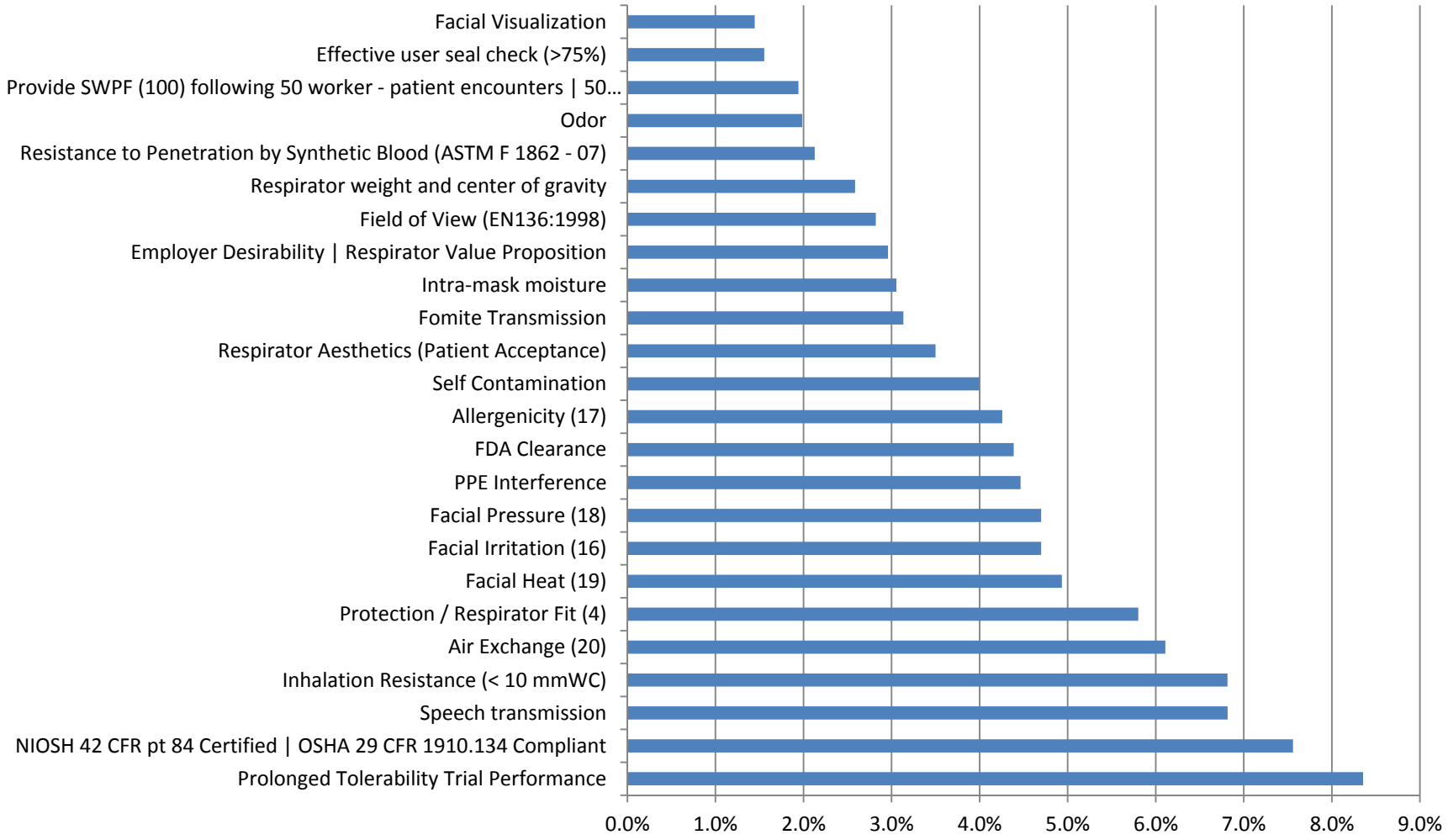
HCW Needs & Benefits



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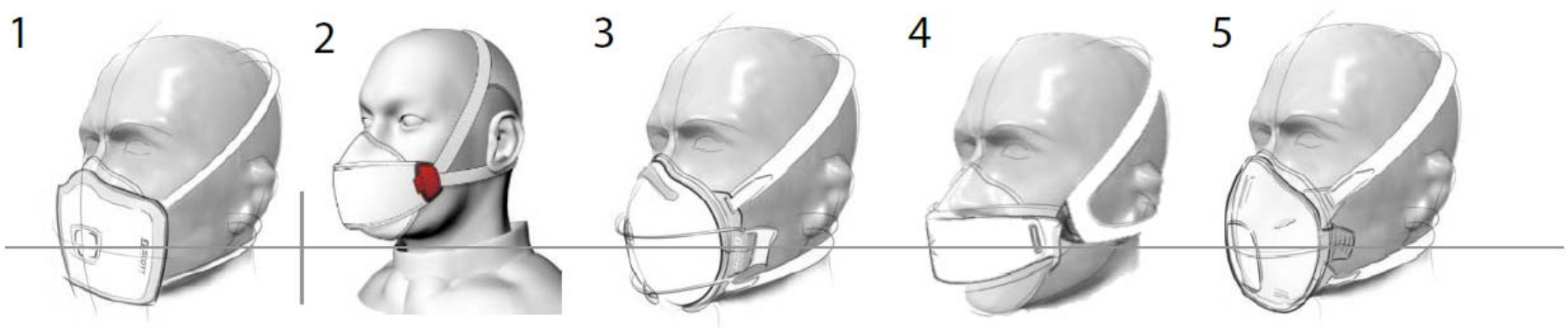
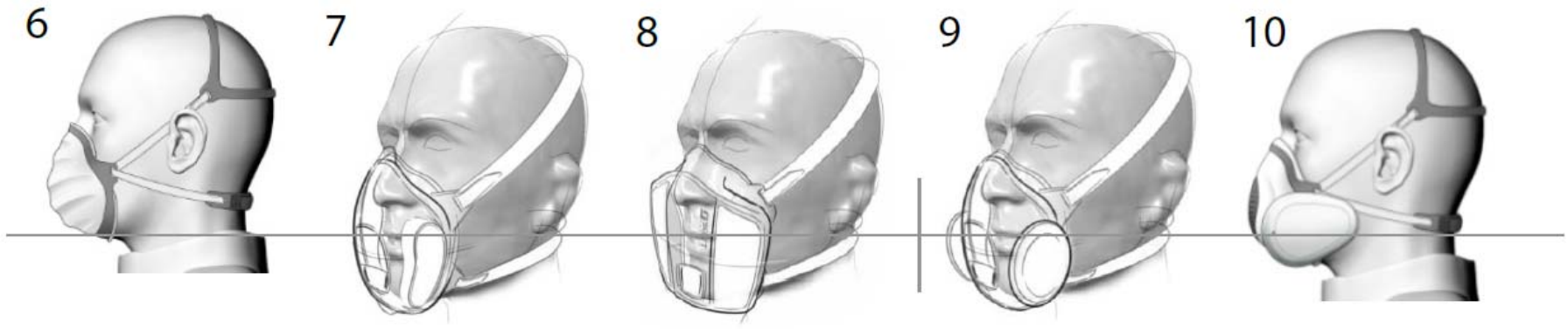
Concept Development – B95 to Hybrid



Disposable

Disposable sections, primary mask remains donned



Disposable sections accessed when doffed

Traditional filter

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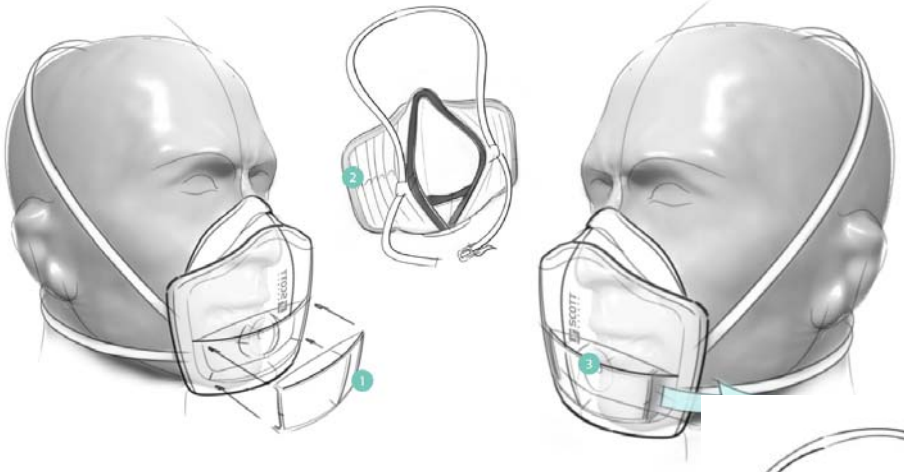
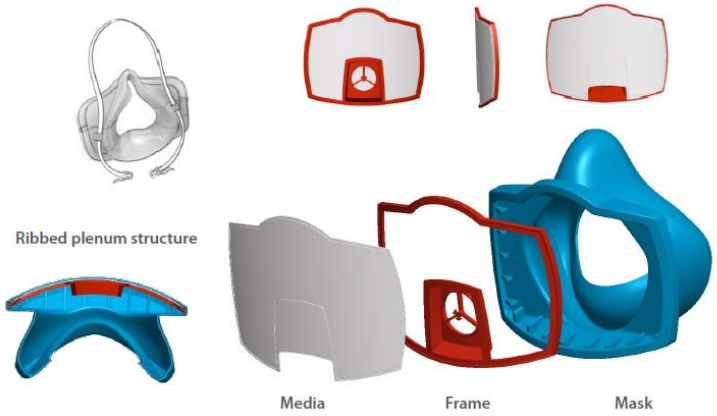
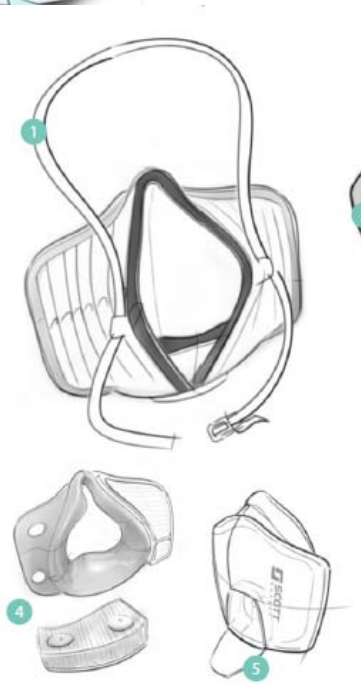
Concept Development

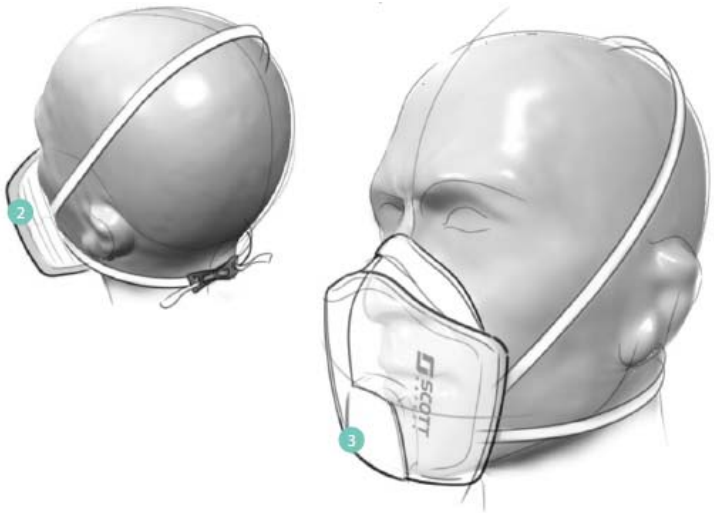
Modular and Scalable – B95 to Hybrid



1. Exhale guard that attaches to the front of the mask to create a 'directed' exhalation.
2. Rear facing filters. This avoids splash contamination directly onto the filter media.
3. Side exhalation is thought to be a better direction when worn by a medical professional leaning over a patient.







1. Single pieces elasticated strap with plastic buckle at rear.
2. Rear facing filters. This avoids splash contamination directly onto the filter media. Filters are simple push in filters that can be changed periodically throughout a work shift.
3. Filter media is brought through from the rear of the mask and heat staked onto the front panel to create a filtered exhale.
4. Optional TPE oronasal with replaceable filter pucks (GSR internal filter).
5. Exhale valve is integrated into the plastic frame construction.

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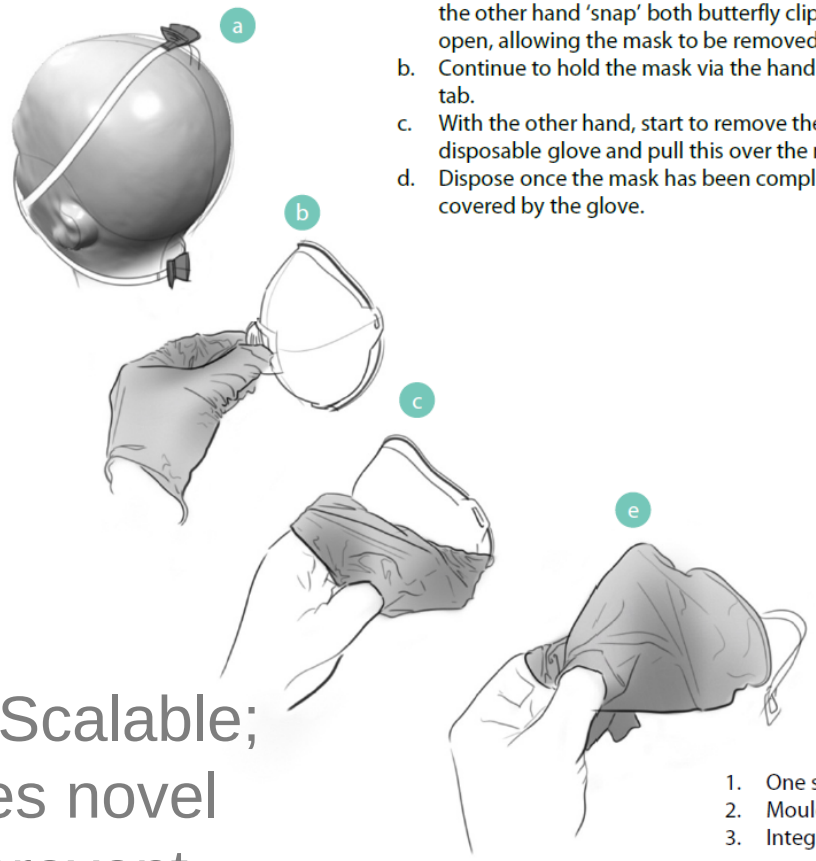
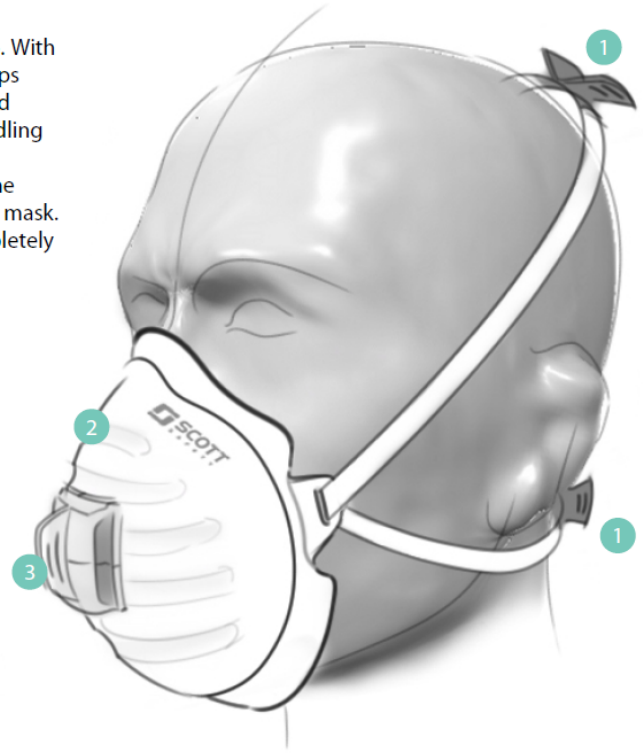
Concept Development

Concept 6



a. Hold mask onto face with handling tab. With the other hand 'snap' both butterfly clips open, allowing the mask to be removed
b. Continue to hold the mask via the handling tab.
c. With the other hand, start to remove the disposable glove and pull this over the mask.
d. Dispose once the mask has been completely covered by the glove.



1. One size elasticated strap with heat staked 'push to snap' butterfly clips
2. Moulded filter media cup with foam gasket seal at the rear.
3. Integrated handling tab as part of the exhale assembly.

Modular and Scalable; incorporates novel doffing to prevent Fomite transmission

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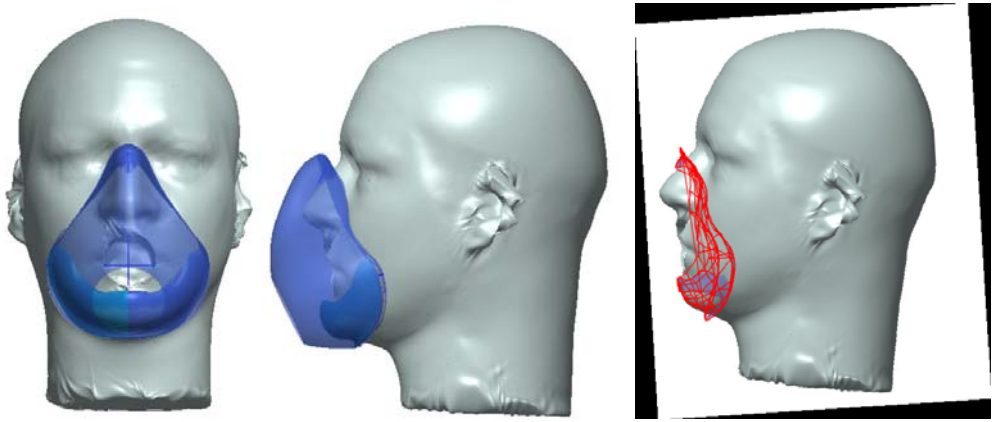
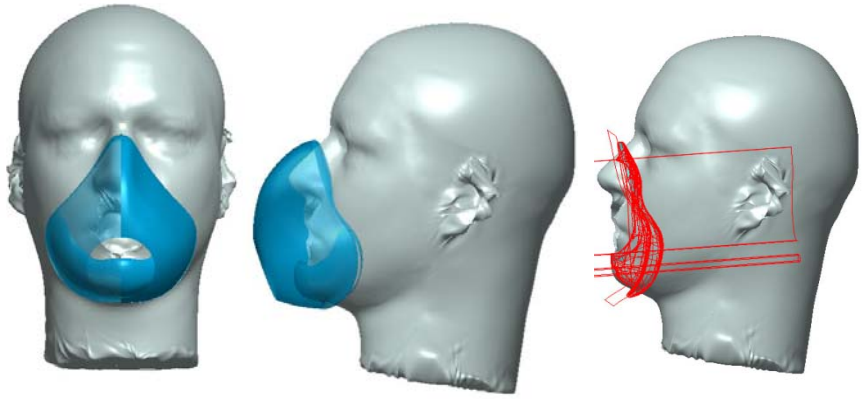
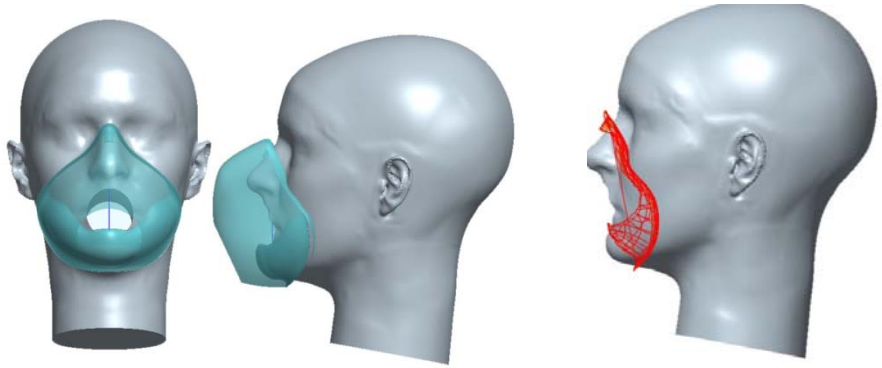
Capability Gaps – Panel Accommodation & Diverse Worker Populations



Large on Large Headform



Medium on Medium Headform



Small on Small Headform

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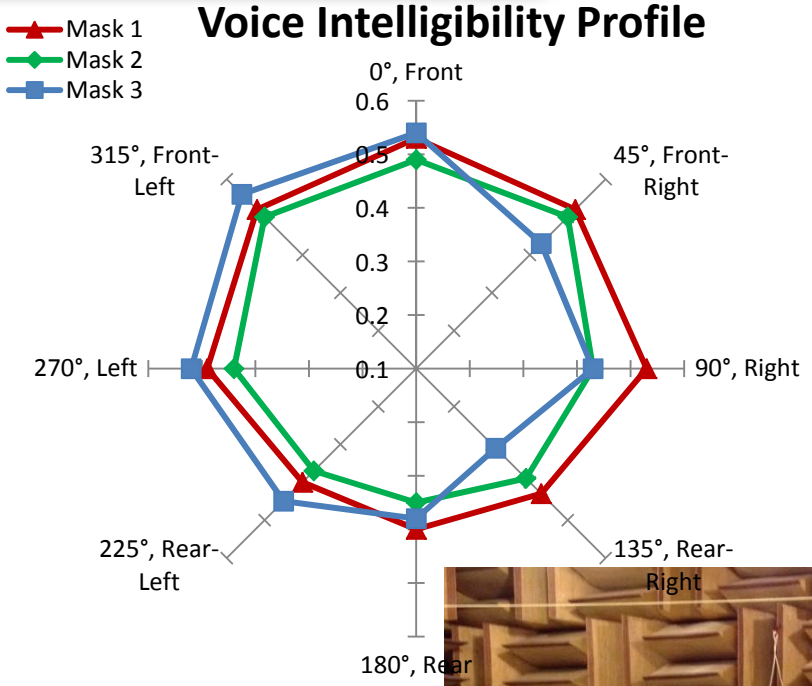
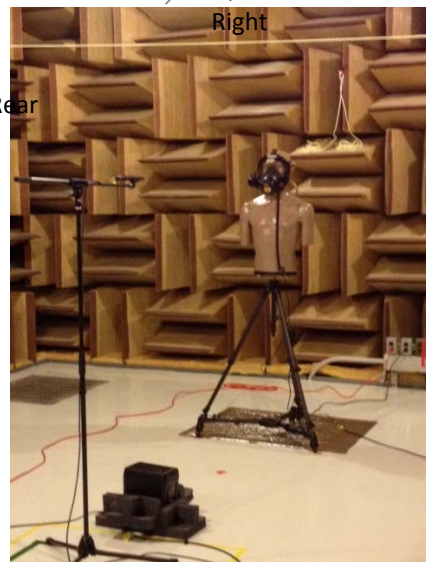
Capability Gaps – Voice Intelligibility

Voice Intelligibility via Speech Transmission Index Methods

- Based on NFPA 1981, 2013 Edition Communications Standard
- Standardized under IEC 60268-16
- Based on concept of fluctuations in speech carry most relevant information in voice intelligibility
- Modulated speech like signal; doesn't saturate as quickly as other methods
- Modified Rhyme Test (MRT) can be subjective, influenced result, long to administer (10-15 minutes per subject)
- Test Plan:
  - Test Signal 97dBA, -15 SNR, Pink Noise 75 dBA
  - Evaluate 360 degree STI in 45 degree increments for sphere of intelligibility (Symons, 2012)
  - N95, B95, Surgical Masks, Elastomeric Half Masks and Hybrid B95s
  - Considers replicates, multiple donnings, multiple measurements
  - Consider modifying pink noise level from 75 dBA to simulate worst case – ICU





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Capability Gaps - Work of Breathing

Work of Breathing (WOB):

Respiratory Protective Devices (RPDs) add resistances to the airway that the respiratory system must overcome while breathing. The work required to overcome such resistances is referred to as the "Work of Breathing".

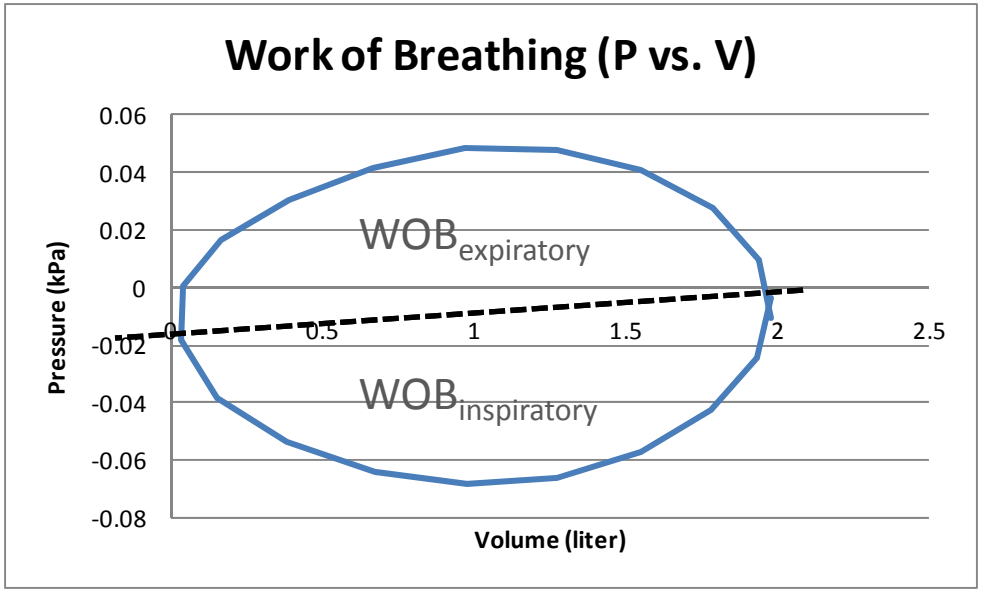
- Another way to define WOB is "**Volume-averaged Pressure**" (or resistive effort). It is the average of pressures contributed by Respiratory Protective Devices (RPDs).

WOB is calculated from the relationship of **Static Pressure** in the mask versus the **Tidal Volume** (total volume per single breath).

Setup:

- Headform for mask mounting
- Bellows based breathing simulator
- Pressure transducer
- Rotary Encoder
- DAQ System (100HZ sampling)

- *Sampling method is based on the most recent version of the ISO/CD 16900-12 standard. ISO breathing rates were used for competitive assessment.*



Sample P-V loop for one of the competitor masks. By integrating the top and bottom curves, $WOB_{inspiratory}$ and $WOB_{expiratory}$ can be calculated.

$$WOB_{total} = WOB_{ins} + WOB_{exp}$$

NOTE: The larger the P-V loop, the greater the WOB: i.e. the more difficult it is to breathe.

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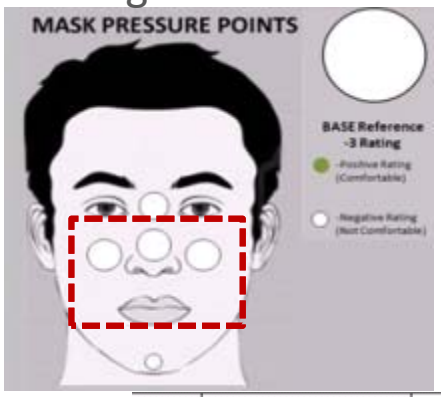
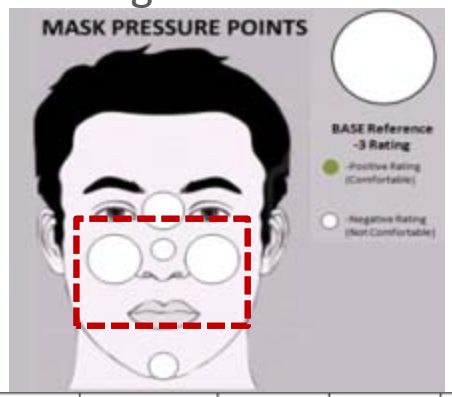
Capability Gaps - Pressure Points and Physical Comfort Ratings

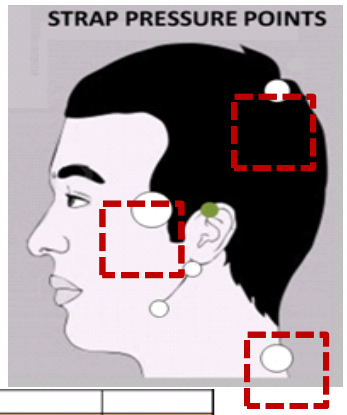
Mfg A MASKS



Mfg B MASKS



ALL MASKS



MASK							
	Nasal Bridge	-0.25	0.33	0.00	-0.67	-0.58	-0.50
	Nose	-0.33	-0.08	-0.50	-0.25	-0.75	-0.17
	Chin (front)	-0.08	0.42	-0.25	-0.17	-0.08	-0.25
	Right Cheek Bone	-0.33	0.17	-0.50	-1.08	-1.08	-0.83
	Left Cheek Bone	-0.33	0.17	-0.50	-1.08	-1.08	-0.83
	Under Chin (fleshy area)	0.42	0.33	-0.08	0.08	-0.25	0.00
	Cheeks (near jaw line)	0.25	0.67	0.08	0.42	-0.08	0.00
STRAPS							
	Temples	-0.08	-0.33	0.33	-0.17	-0.42	0.00
	Cheeks (near jaw line)	0.25	0.42	0.08	-0.08	-0.08	0.00
	Above Ear	0.08	0.25	-0.08	0.00	0.08	0.00
	Below Ear	0.25	0.25	0.42	0.08	-0.08	0.25
	Top of Head	0.25	0.25	0.00	0.08	-0.17	0.00
	Neck	0.08	0.33	0.00	0.00	-0.25	0.25

*had the best comfort scores for the masks, but the strap staples were a negative feature.

*had the lowest scores for strap pressure points.

Mfg A Masks:

- Overall, mildly negative to slightly negative ratings on pressure point comfort.
- The conformal mask was the only mask to obtain positive ratings in the nose, cheek and chin areas.

Mfg B Masks:

- Overall, very negative to mildly negative ratings on pressure point comfort.
- Most common complaint was rubbing/pinching/pressure in the upper cheek/sinus areas and the nose bridge. Observed over all 3 masks.
- The rigid masks moved while the subject talked, causing rubbing on the chin and nose bridge.

Straps:

- Overall, mildly negative to slightly negative ratings on pressure point comfort.
- Most common complaint was rubbing/pinching/pressure in the temple area. This was caused by the staples used to attach straps to mask.
- Negative ratings were observed with the elastic band type straps. They tended to pull hair (especially long hair) and rub the back of the neck.

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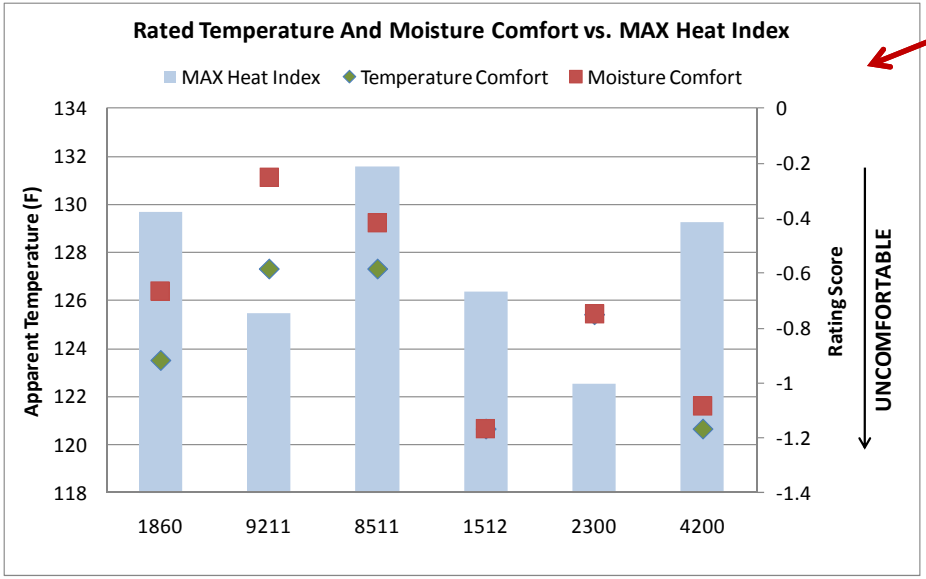
Capability Gaps - Microclimate Temperature and Humidity

Quantitative heat and moisture data was measured in the 'deadspace' of each mask during the Tolerability Study using an iButton Sensor (Maxim Integrated™).

Evaluated the maximum values for the overall testing period (10 minutes) and broken individual exercise:

- Mask Temperature (° F)
- Mask Relative Humidity (RH%)
- Mask Calculated Heat Index (°F)

Heat Index- is a meteorological term used to describe the human-perceived equivalent temperature (how it feels). It is calculated using only air temperature and relative humidity.



User rated Temperature and Moisture comfort ratings do not represent measured data of Heat Index in mask deadspace.

Deadspace Temperature and Moisture **may not** be the only factors affecting user perception of heat and moisture comfort in the mask.

- •CO2/O2
- •Breathing Resistance
- •Airflow Distribution
  (moving air causing cooling sensation over skin)
- •High WOB Values

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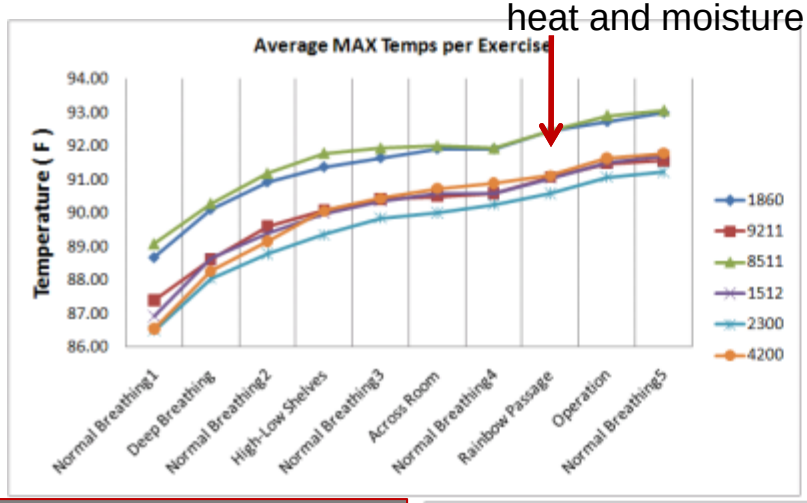
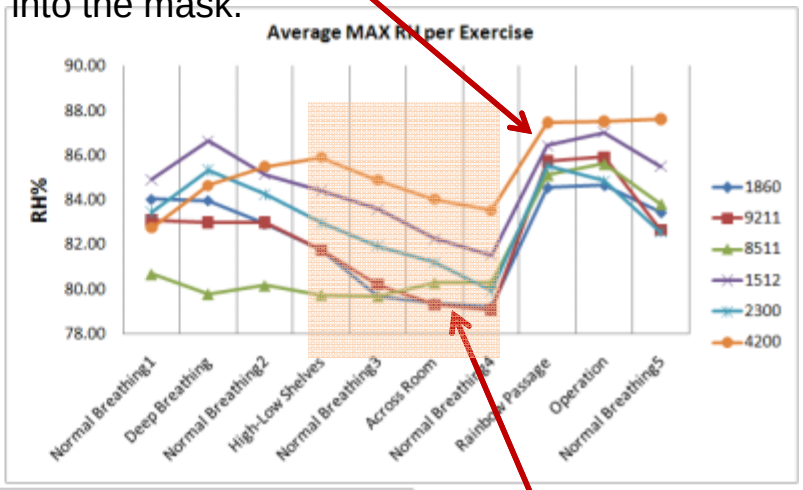
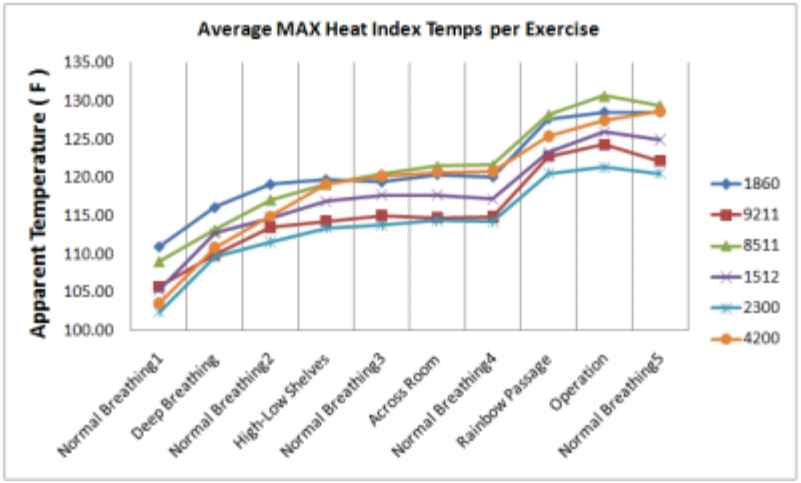
Capability Gaps – Microclimate Temperature and Humidity

Talking adds a significant amount of heat and moisture into the mask.







Between High-Low Shelves and Talking, there is a decrease in RH%. This could be caused by moving air across the mask while performing these tasks.

There appears to be the development of a boundary layer condition around the outside surface of the mask.

This boundary condition could lead to stagnation of air movement, hindering exhaled air to fully disperse through and away from the front surface of the mask.

Head movements aid in the reduction of moisture and stabilization of temperature within the mask's dead space.

NEEDS FURTHER INVESTIGATION

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Further Research/Next Steps

- CFD/Airflow Distribution & Boundary Layer Location
- Optimize CO2/O2 Levels inside the Mask
- Heat Dissipation and Exhalation Valve Embodiments
- Incorporation of Novel Materials to Facilitate Heat Transfer inside the Microclimate
- Reduced Work of Breathing via Filtration Material Selection
- Initial Production B95 and B95 Hybrid for Design Validation
- Intuitive Donning/Doffing and Seal-Checks, Comfort/Tolerability Trials
- STI vs. MRT – N95, B95, Surgical Masks, Elastomeric Half Masks and Hybrid B95s
- Protection Factors in SWPF Studies
- Clinical Trials, Performance for Comfort/Tolerability
    - NIOSH/NPPTL Study
    - Malcolm Randall VA Medical Center Simulation Laboratory

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Any Questions?

Thank You!